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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/556,658

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Gary Rheinheimer

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SIEMENS CORPORATION
INTELLECTUAL PROPERTY DEPARTMENT
170 WOOD AVENUE SOUTH
ISELIN, NJ 08830

EXAMINER

PAJOOHI, TARA S

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/556,658	Applicant(s) RHEINHEIMER ET AL.	
	Examiner Tara S. Pajoohi	Art Unit 2886	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/9/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Acknowledgement is made to the amendment filed on 9/09/2008.
2. Claims 1-30 are still pending.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 1, 7-19, 21 and 23-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Shaeef (U.S. Patent No. 6,239,445)** in view of **Shen et al. (U.S. Patent No. 5,905,808)**.
5. Considering **claims 1, 21 and 28**, Shaeef discloses (col. 3-4) and shows in figure 2, an optical inspection machine (10) wherein a row of colored segments (50) simulate color of reagent pads on a liquid carrier (i.e., liquid sample carrier) such that the segments can be illuminated by the readhead (108 and 112) of the optical inspection machine (10).

Shaeef fails to specifically disclose a method and apparatus for verifying proper operation of an optical inspection machine, comprising: a row of colored segments that simulate color of reagent pads on a liquid carrier containing types of analytes at known concentrations, and wherein the row of colored segments are positioned to simulate placement of reagent pads on a liquid carrier such that the segments can be illuminated by the readhead of the optical inspection machine.

Shen discloses (abstract and col. 3, line 55 – col. 5, line 67) and shows in figure 1, a method and apparatus for verifying proper operation (i.e., to verify if the system is calibrated or if it require maintenance or repair of the instrument, col. 10, lines 42-49) of an optical inspection machine (30), comprising: a row of colored segments that simulate color of reagent pads on a liquid carrier containing types of analytes at known concentrations (i.e., calibration cassette (10) includes a row of colored segments (22a-22d and 16a-16g) that simulate known types of agglutination reactions, col. 5, lines 7-12), and wherein the row of colored segments are positioned to simulate placement of reagent pads on a liquid carrier such that the segments can be illuminated by the readhead (34) of the optical inspection machine and wherein the method is repeated on a predetermined basis and the results provided by the optical inspection machine are recorded (i.e., recorded in storage subsystem (42)).

It would have been obvious to one having ordinary skill in the art to use a row of colored segments that simulate color reagent pads on a liquid carrier containing known types of analytes at known concentrations to verify proper operation of an optical inspection machine as taught by Shen in the method of Shaeef, since Shen teaches that regular calibration of the system will provide consistent test results.

6. Considering **claim 7**, Shaeef discloses (col. 3, line 66 – col. 4, line 1) the row of colored segments (50) are provided on an insert (48) secured to a housing (22).

7. Considering **claim 8**, Shaeef discloses (col. 3-4) the insert (48) is secured within the housing (22) and the housing includes a window (28) for allowing the insert to be illuminated by the readhead (108 and 112) of the optical inspection machine (10).

8. Considering **claims 9, 10 and 23**, Shaeef discloses (col. 4, lines 1- 12) the insert (48) is made from paper and the colored segments are printed ink (i.e., commercially available Multistix reagent strip is known to be made of paper and the colored segments are printed ink).

9. Considering **claims 11 and 24**, Shaeef fails to specifically disclose the colored segments include non-white colored segments separated by white segments.

Shen shows in figure 1, the colored segments include non-white colored segments (22a -22d) separated by white segments.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use non-white colored segments separated by white segments as taught by Shen in the system and method of Shaeef, since Shen discloses in column 3, that it helps monitor the long term stability of the system.

10. Considering **claims 12, 13, 25 and 26**, the modified method and system of Shaeef discloses (col. 4, lines 48-65 of Shen) and shows in figure 1, the non-white colored segments include gray bands (16a-16g) of varying intensities used to confirm that a detector linearity of an optical inspection machine is correct (i.e., to test the symmetry of the light conditions of the imaging system).

However the modified method and system of Shaeef fails to specifically disclose the non-white color segments include colored stripes used to confirm that colored stripe detection and amplitude accuracy of the optical inspection machine is correct or that the non-white colored segments include orange, green and aqua color bans used to confirm that a LED characterization of an optical inspection machine is correct.

However using “non-white color segments, such as colored stripes to confirm that colored stripe detection and amplitude accuracy of the optical inspection machine is correct” or “non-white

colored segments, such as orange, green and aqua color bans to confirm that a LED characterization of an optical inspection machine is correct” is an obvious variation of using “non-white colored segments, such as gray bands of varying intensities to confirm that a detector linearity of an optical inspection machine is correct” since they are all well known conventional methods to facilitate calibration.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use various non-white colored segments for calibration purposes depending on the type of calibration is suitable for the optical inspection machine.

11. Considering **claims 14 and 27**, Shaeef fails to specifically disclose the non-white colored segments include gray bands of varying intensities used to confirm that a detector linearity of an optical inspection machine is correct.

Shen discloses (col. 4, lines 48-65) and shows in figure 1, the non-white colored segments include gray bands (16a-16g) of varying intensities used to confirm that a detector linearity of an optical inspection machine is correct (i.e., to test the symmetry of the light conditions of the imaging system).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use gray bands of varying intensities to confirm that a detector linearity of an optical inspection machine is correct as taught by Shen in the system and method of Shaeef, since Shen discloses in column 3, that it helps monitor the long term stability of the system.

12. Considering **claim 15**, Shaeef discloses (col. 3, lines 16-37) and shows in figure 2, the housing includes orientation features (34) that mate with orientation features of a tray assembly (i.e., holes formed in the bottom surface of the reagent cassette (22)) for guiding the apparatus into the optical inspection machine, so that the apparatus can be correctly orientated in the tray assembly.

13. Considering **claim 16**, the modified system of Shaeef discloses (col. 3, lines 16-37) and shows in figure 2, orientation features (34) to mate with the bosses of the tray assembly but fails to specifically disclose different sized indents positioned to receive corresponding different sized bosses of the tray assembly.

However it would have been obvious to use different sized orientation features to ensure that there is only one proper orientation for the tray assembly and therefore limiting the possibility of incorrectly inserting the tray assembly into the optical inspection apparatus either.

14. Considering **claim 17**, Shaeef discloses (col. 3-4) a tray assembly (20) including a support tray (22) for insertion into an optical inspection machine (10) and an insert (46) that fits in the support tray (22), and wherein the insert has a surface contoured to receive the row of colored segments (50).

15. Considering **claims 18 and 19**, Shaeef discloses (col. 3-5) an optical inspection machine (10) comprising: an opening (18) into which the tray assembly (20) and the apparatus are retracted, an inspection location within the opening (18) for receiving the apparatus, a light source (108) for illumination the apparatus when the apparatus is received in the inspection location and a detector (112) for receiving light reflected off the apparatus from the light source.

16. Considering **claim 29**, Shaeef discloses (col. 3, lines 16-36) and shows in figure 2, the housing (22) comprises a top piece defining the window (28) for allowing the insert (48) to be illuminated by the readhead of the optical inspection machine, and a bottom piece secured to the top piece with the insert secured between the top and bottom pieces, wherein the bottom piece includes an end wall and side walls extending toward the top piece and that correctly position the insert with respect to the window.

17. Considering **claim 30**, Shaeef discloses and shows in figure 5, wherein the top piece of the housing includes on a top surface thereof offset parallel rows of bosses (42) extending from opposite ends of the window.

18. **Claims 2-6, 20 and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Shaeef (U.S. Patent No. 6,239,445)** in view of **Shen et al. (U.S. Patent No. 5,905,808)** and further in view of **Gross (U.S. Patent No. 4,867,946)**.

19. Considering **claims 2-6 and 22**, the modified system and method of Shaeef discloses (col. 3, lines 60-65 of Shaeef) the reagent strip holder (40) has a central channel (43) formed therein which is sized to conform to the shape of a reagent strip (46) to keep the reagent strip properly aligned within the optical inspection machine

However, the modified system and method of Shaeef fails to specifically disclose offset parallel rows of indicators extending from ends of the row of colored segments wherein the indicators comprise square black bosses having flat top surfaces which are used to confirm that an optical train of an optical inspection machine is properly aligned.

Gross discloses (col. 1, line 53 – col. 2, line 64) and shows in figure 2, a device for evaluating test strips comprising parallel rows of black indicators (5) extending from the rows of colored segments (9) and guide grooves (4), all used to properly align the apparatus (i.e., position marks).

It would have been obvious to one having ordinary skill in the art to use various types/size/color of alignment marks to properly align an optical inspection machine as taught by Gross in the modified method and system of Shaeef, since Gross teaches that the position marks will allow the optical inspection machine to be easily aligned and suitable for test strips in mobile facilities.

Still lacking the limitations of the indicators comprise bosses having flat top surfaces and that the indicators are square.

However, it would have been obvious matter of design choice to change the shape or the indicators such that the indicators have bosses with flat top surfaces or to be square since such a modifications to the indicators would have involved a mere change in shape and it appears that the invention would perform equally well without such a modification and would be well within the level or ordinary skill in the art. It would have been further obvious in order to provide for easier alignment within the optical inspection machine.

20. Considering **claim 20**, the modified system of Shaeef fails to specifically disclose the use of different wavelengths to illuminate the test strip.

Gross discloses (col. 1, line 53 - col. 2, line 30) the use of different wavelengths to illuminate the test strip.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use different wavelengths to illuminate the test strip as taught by Gross in the modified system of Shaeef, since Gross teaches that using multiple light sources are particularly suitable for large quantity investigations in chemical/medical test laboratories.

Response to Arguments

21. Applicant's arguments with respect to claims 1-30 have been considered but are moot in view of the new ground(s) of rejection.

22. However for further clarification, in response to applicant's arguments, the recitation of "an apparatus for verifying proper operation of an optical inspection machine" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use

of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

1. Tara S. Pajoochi

Any inquiry concerning this communication or earlier communications from the examiner should be directed to whose telephone number is (571)272-9785. The examiner can normally be

reached on Monday - Thursday 9:00 a.m. - 5:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tarifur R. Chowdhury can be reached on 571-272-2287. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Tara S. Pajoochi
Patent Examiner

TSP

/Roy M. Punnoose/
Primary Examiner, Art Unit 2886